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**EP-A- 0 274 129**  
**FR-A- 2 340 078**  
**US-A- 4 652 258**

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## Description

### FIELD OF THE INVENTION

This invention relates to balloon dilatation catheters and particularly to such catheters as are used in percutaneous transluminal coronary angioplasty.

### BACKGROUND OF THE INVENTION

Dilatation catheters, and particularly, those used for percutaneous transluminal coronary angioplasty (PTCA), typically include an elongate flexible shaft of the order of 150 cm long having a dilatation balloon mounted to the distal end of the shaft and an inflation lumen extending longitudinally within the shaft from its proximal end to the interior of the balloon so that the balloon may be inflated and deflated. Typically, such PTCA catheters also are provided with a full length guidewire lumen that is open at the distal tip of the shaft at a distal outlet opening. The proximal end of the guidewire lumen is open at the proximal end of the catheter. The guidewire lumen receives a guidewire which, when the guidewire and catheter are placed within a patient's artery, can be manipulated to guide the wire and catheter to the desired branch of the patient's arteries.

Typically, the balloon dilatation catheter and guidewire are guided to the entrance to the coronary arteries by a previously placed guide catheter. The guide catheter commonly is percutaneously inserted into the patient's femoral artery and is advanced along the aorta toward the heart. The guide catheter typically is provided with a preshaped distal tip adapted to remain at the coronary ostium leading to the coronary artery. Once placed, the guide catheter provides direct, quick access to the entrance to the coronary arteries.

It is common during a PTCA procedure for the physician to exchange the balloon catheter for another catheter, for example, if it is desired to change balloon sizes. This may occur, for example, if the physician initially performed a partial dilatation with a small diameter balloon and then wished to further dilate the patient's artery by using a catheter having a larger balloon. Such a catheter exchange may be accomplished in several ways. In one technique, the conventional guidewire which may be approximately 175 cm long is removed from the in situ balloon catheter and is replaced with a longer exchange wire, typically about 300 cm long. The length of the exchange wire that extends out of the patient is greater than the length of the balloon catheter thus providing a means by which the guidewire may be grasped at all times to prevent inadvertent withdrawal of the guidewire as the catheter is withdrawn. Once the catheter is

withdrawn over the exchange wire, the next catheter can be threaded over the exchange wire and inserted into the patient, the exchange wire providing a direct path to guide the catheter to the portion of the artery to be dilated. If desired, the exchange wire then may be removed and replaced with a shorter conventional wire, although some physicians may prefer to permit the exchange wire to remain in place for the remainder of the procedure.

Another technique omits the necessity for an exchange wire by providing a guidewire extension that is attached to the proximal end of the guidewire thereby effectively extending the length of the guidewire that protrudes out of a patient sufficiently to permit the catheter to be withdrawn and a new catheter to be threaded back into the patient without losing guidewire position.

Still another technique for performing a catheter exchange is that described in "New Instruments for Catheterization and Angiocardiography" by Bjorn Nordenstrom, *Radiology*, Vol. 85, 1965, pp. 256-259, which describes a catheter having a relatively short guidewire lumen at the distal end of the catheter, the guidewire lumen having a proximal terminal opening located distally of the proximal end of the catheter shaft. In this arrangement, the guidewire passes through the catheter shaft only for a segment of the length of the shaft. The catheter can be moved along the guidewire in the fashion of a "monorail". Because the guidewire lumen is relatively short and is considerably shorter than the overall length of the catheter, the catheter can be withdrawn from the patient over the original guidewire without dragging the guidewire out of the artery together with the catheter because the length of guidewire protruding from the patient is longer than the length of the guidewire lumen of the catheter. Thus, a portion of the guidewire is exposed at all times and may be grasped by the physician.

Although the use of the monorail system facilitates catheter exchanges, the PTCA catheters in which the monorail system have been incorporated have presented some difficulties. One of the problems presented is that because the guidewire only extends through a relatively small portion of the overall length of the catheter, the remaining portion of the catheter shaft is unsupported by the guidewire. When the balloon catheter and guidewire are advanced through the guide catheter by pushing the catheter shaft, the unsupported portion of the catheter shaft tends to buckle within the guide catheter. Buckling of the catheter shaft within the guide catheter increases the number and area of points of contact between the catheter shaft and the inner surface of the guide catheter lumen, thus increasing friction and causing the balloon

catheter to bind up in the guide catheter and impairing the ability of the catheter to be pushed along the guidewire. The tendency to become bound up in the guide catheter increases with the extend to which the catheter is advanced through the guide catheter and prevents the catheter from being advanced into distal coronary vasculature. The tendency for the dilatation catheter shaft to buckle is particularly acute in the region of the aortic arch.

EP-A-0 274 129 (Horzewski) discloses a balloon dilatation catheter having proximal, intermediate and distal segments, the intermediate segment being plastic and elongate and attached to the distal end of the proximal segment and having two lumens formed therethrough including an inflation lumen terminating in an outlet port and having a second guidewire lumen extending parallel to the first lumen and being adapted to receive a guidewire, the guidewire lumen having a proximal opening in the region of the juncture of the intermediate and proximal segments, the distal segment being attached to the distal end of the intermediate segment and defining an elongate lumen in communication with and a continuation of the distal end of the guidewire lumen of the intermediate segment, and terminating, at its distal tip, in a distal outlet, a dilatation balloon having proximal and distal ends, the distal end of the balloon being mounted on the distal segment and the proximal end of the balloon being mounted on the intermediate segment, the interior of the balloon being in communication with the outlet port of the inflation lumen. The proximal section of this catheter is made of a flexible plastics material and has two lumens in it, one of which receives a guidewire and the other a stiffener which is inserted therein to prevent the proximal section from buckling during insertion and removal from the guide catheter. Because of this construction, the proximal section has to be of a larger diameter so it suffers from the disadvantage that it occupies a relatively large volume in the guide catheter and thereby hinders the flow of radiopaque fluid therethrough.

It is among the general objects of the invention to provide an improved PTCA catheter having a rapid exchange feature which avoids the foregoing and other difficulties.

According to claim 1, the present invention provides a catheter which is characterised by the features that the proximal segment has a single inflation lumen extending therethrough and is substantially smaller in diameter than the intermediate segment, the proximal segment having sufficient column strength to resist buckling when advanced through a patient's arteries whereby when a guidewire is received in the guidewire lumen the catheter will have continuous column support fully

along its length from the proximal end of the tubular shaft to the distal outlet of the distal segment.

The preferred catheter of the present invention is formed from a composite shaft that includes an elongate proximal segment formed from a relatively stiff metal tube and defining an inflation lumen, an intermediate, shorter segment formed from a more flexible, plastic material and having two lumens, and a third single lumen distal segment. The intermediate segment includes an inflation lumen that is a continuation of the inflation lumen of the proximal segment and a second, parallel guidewire lumen. The third, distal tubular segment is formed from flexible plastic material and has a single lumen which is a continuation of the guidewire lumen in the intermediate segment and opens at a distal outlet tip. The dilatation balloon is mounted on the distal end of the catheter with its proximal end mounted to the intermediate segment and its distal end mounted to the distal segment. The guidewire lumen has a proximal opening proximally of the balloon and communicates with the lumen of the distal segment and distal outlet opening distally of the balloon.

The intermediate and distal segments are preferably of a combined length, between about 35cm to 45cm, such that with the catheter advanced into the most remote distal portions of the coronary anatomy, the flexible plastic intermediate segment will extend over the aortic arch of the patient. The juncture of the relatively stiff proximal segment and the more flexible intermediate segment thus remains proximally of the aortic arch so that the relatively stiff elongate proximal section extends generally along a straight line from the femoral artery into the descending aorta, but not so far as into the aortic arch. The moderately flexible proximal segment is sufficiently stiff and is self-supporting so that it will not buckle in the guide catheter as the catheter is pushed in a distal direction. Additionally, the intermediate and distal segments of the catheter are fully supported by the guidewire that extends through the guidewire lumen and thereby provides substantial support for the intermediate and distal segments of the catheter. The catheter construction does not tend to bind up within the guide catheter and thereby facilitates advancement of the distal balloon end of the catheter into more distal regions of a patient's coronary anatomy. Moreover, because the cross-section of the metal tubular proximal segment is relatively small, it presents reduced obstruction through the guide catheter to a flow of radiopaque contrast liquid and, thereby, makes it easier for the physician to inject contrast liquid into the patient's coronary arteries in order to visualize them fluoroscopically.

It is among the general objects of the invention to provide an improved rapidly exchangeable balloon dilatation catheter.

Another object of the invention is to provide a rapidly exchangeable balloon dilatation catheter which is provided with axial support along the full length of the catheter.

Another object of the invention is to provide a rapidly exchangeable catheter having a relatively flexible distal portion that receives a guidewire and is of sufficient length that it can extend from the distal coronary anatomy over the aortic arch and into the descending aorta.

A further object of the invention is to provide a rapidly exchangeable catheter having an elongate moderately flexible self supporting proximal section and at least one distal section that is more flexible and has a guidewire lumen extending therethrough whereby the guidewire may support said distal segments.

A further object of the invention is to provide a rapidly exchangeable catheter which has a reduced tendency to buckle within the guide catheter.

Another object of the invention is to provide a rapidly exchangeable catheter which provides reduced friction in the guide catheter.

A further object of the invention is to provide a rapidly exchangeable catheter which better enables the physician to advance the distal end of the catheter into the distal coronary anatomy of a patient.

#### DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. 1 is a fragmented illustration of the catheter;

FIG. 2 is an enlarged illustration of the catheter;

FIG. 3 is a diagrammatic illustration of a patient showing the manner in which a balloon catheter is advanced from the femoral artery through the aorta to the patient's heart;

FIG. 4 is an illustration of the aorta leading from the heart and coronary arteries with a guide catheter in place and the catheter of the present invention extending through the guide catheter;

FIG. 5 is a cross-sectional illustration of the two lumen segment of the intermediate segment of the catheter as seen along the line 5-5 of FIG. 2; FIG. 6 is an enlarged illustration of the proximal end of the balloon and its point of attachment to the intermediate segment;

FIG. 7 is a sectional longitudinal illustration of the catheter in the region where the proximal

metal tubular segment is joined to the intermediate more flexible plastic segment; and

FIG. 8 is an enlarged longitudinal sectional illustration of the distal end of the catheter showing the balloon and the manner of its attachment to the intermediate and distal segments.

#### DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENT

FIG. 3 illustrates, diagrammatically, a conventional over-the-wire balloon dilatation catheter 10 and a guidewire 12 inserted into the patient's vasculature through a guide catheter 14. The guide catheter 14 is initially placed, percutaneously, into the patient's femoral artery 16 and is advanced along the descending aorta 18 over the aortic arch 20 and into the ascending aorta 22 that leads from the heart 24. As will be appreciated by those skilled in the art, the distal end of the guide catheter is specially shaped so that the distal tip 23 of the guide catheter will easily lodge in the entrance to the right 25 or left 27 coronary artery (see FIG. 4).

When it is desired to exchange the balloon catheter 10 for another, it is important that the guidewire 12 be maintained within the patient's artery so that it may guide the next succeeding catheter quickly and efficiently to the intended site in the patient's vascular system. Typically, the clearances between the guidewire 12 and the inner lumen of the catheter 10, coupled with the bends which the catheter 10 and guidewire 12 must follow along the patient's artery are such that withdrawal of the catheter 10 tends to drag the guidewire 12 out with the catheter 10. In order to maintain the guidewire 12 in place while the catheter 10 is withdrawn, it is necessary to hold the guidewire 12 by its proximal end while withdrawing the catheter 10 over the guidewire 12.

Among the techniques for facilitating a catheter exchange is the use of a monorail-type of catheter in which the guidewire lumen in the catheter extends only over a relatively short length of the catheter at the distal end of the catheter. Because the guidewire lumen is shorter than the portion of the guidewire that protrudes out of the patient, some part of the guidewire is always exposed and may be grasped to maintain guidewire position. With the monorail system, it is unnecessary to use exchange wires or other devices to increase the effective length of the guidewire in order to perform a catheter exchange.

FIG. 2 is a fragmented illustration of a catheter in accordance with the invention. The catheter 26 includes an elongate proximal segment 28 which is formed from metallic hypodermic tubing, preferably stainless steel. The proximal segment may be of

the order of 100 to 110 cm long. The tubing 28 may be of the order of 0,56 mm (0.022") outer diameter with a wall thickness of about 0,076 mm (0.003"). The catheter 26 also includes an intermediate segment 30 attached at its proximal end to the distal end of the metal tube 28 and being shorter in length than the metal tube 28. The catheter also includes a distal segment 32 (FIGS. 2 and 8) attached to the distal end of the intermediate segment 30. A dilatation balloon 34 is mounted on the distal segment 32 as will be described. The metallic tubular proximal segment 28 defines a lumen 36 (FIG. 7) that extends fully through its length. A luer fitting 38 is attached to the proximal end of the tubing 28 to connect the lumen 36 with an inflation/deflation device, such as a syringe (not shown). The lumen 36 communicates with a lumen 40 in the intermediate segment 30. The lumen 40 terminates at a port 42 disposed within the balloon 34. Thus, the balloon 34 may be inflated and deflated through the inflation/deflation lumens 36, 40 in the metal tube 28 and intermediate segment 30, respectively.

As will be described, the metal tubular segment 28 provides for a high degree of column strength and enables the catheter to be pushed from its proximal end without buckling. The metal tube 28 may be coated with a thin film of lubricious material, such as Teflon, polytetrafluoroethylene.

The flexible plastic intermediate segment 30 may be an extruded tube of suitable plastic such as high density polyethylene. The intermediate segment 30 may be of the order of 1,14 mm (.045 inches) outer diameter. The length of the intermediate segment 30 is between about 30 to 40 cm for reasons discussed below. The intermediate segment 30 has two lumens including the inflation lumen 40 which may be somewhat D-shaped as illustrated in FIG. 5. The other lumen 44 may be circular as shown in FIG. 5 and is adapted to receive the guidewire 12. The guidewire lumen 44 may be of the order of 0,51 mm (.020 inches) diameter. The guidewire lumen terminates in a proximal opening 46 so that the guidewire is exposed proximally of the intermediate segment 30. Thus, the guidewire may extend within the guide catheter 14 in parallel to and outside of the proximal segment 28.

The distal segment 32 of the catheter is formed from a separate length of single lumen tubing which may be extruded from a relatively flexible plastic material such as low density polyethylene. The distal segment 32 is circular in cross-section and has a circular lumen 48 FIG. 6 which is an extension of the guidewire lumen 44 in the intermediate segment 30. The distal tip of the distal segment 32 is open at a distal outlet orifice 33 FIG. 8. The distal segment 32 may be attached

by fusing its proximal end to the distal end of the intermediate segment 30 while maintaining continuation of the guidewire lumen 44, 48 and the opening 42 of the inflation lumen 40 by inserting mandrels in those lumens during the fusion process. A highly radiopaque marker band preferably is mounted on the distal segment 32 and is encapsulated in an overlying thin polyethylene sleeve 37, the sleeve 37 extending proximally over the joint 39 between the intermediate segment 30 and distal segment 32. The sleeve 37 also is heat fused to the shaft. The distal segment 32 may have a wall thickness of the order of 0,089 mm (.0035 inches) thereby making it more flexible than the more massive intermediate segment 30. A radiopaque marker band 35 formed from an appropriate radiopaque material, such as gold or platinum, may be mounted on the distal segment 32.

The balloon 34 is mounted on the distal region of the catheter. The balloon 34 may be formed from a suitably flexible strong and relatively inelastic material such as polyethylene terephthalate. The balloon may be formed in a procedure described in US-A-4,490,421 to Levy. The balloon may be of the order of 20 mm long and may have a balloon diameter when inflated of from about 1.5 mm to 4.0 mm. The wall thickness may be of the order of 0,013 to 0,026 mm (0.0005" to 0.001"). The balloon includes an elongate cylindrical portion having integral tapering conical sections 49, 51 at each of its proximal and distal ends. Each of the conical sections merges into a small diameter cylindrical neck, the neck 52 at the proximal end of the balloon being larger in diameter than the neck 54 at the distal end. The proximal neck 52 is mounted on the distal region of the intermediate segment 30 and the distal neck 54 is mounted on the distal portion of the distal segment 32. The neck portions 52, 54 are securely bonded to the intermediate and distal segments 30, 32, respectively, by an appropriate adhesive such as an epoxy.

The manner in which the catheter of the present invention is used will be appreciated from FIGS. 3 and 4. In a typical procedure, the femoral artery 16 is accessed percutaneously by a hollow needle. After inserting the needle into the femoral artery, a relatively large diameter guidewire (about 0,97 mm (0.038") diameter) is advanced through the needle and into the femoral artery. The needle is removed and an introducer sheath and dilator are placed inside the artery. The dilator is then removed. The guide catheter is inserted over the guidewire and is advanced along with the guidewire to the ascending aorta when the 0,97 mm (.038") guidewire is removed. The distal end of the guide catheter 14 is shaped specially to be easily inserted into the entrance of one of the two coronary ostia to access either the right or left main coro-

nary arteries. FIG. 4 illustrates a guide catheter 14 seated in the left coronary ostium. Once the guide catheter is in place, the 0.97 mm (0.038") guidewire may be removed. The guide catheter 14 then is ready to receive the dilatation catheter and its small diameter (e.g., 0.25 - 0.46 mm (0.010"-.018") diameter) guidewire.

In placing the small diameter steerable guidewire 12 and the conventional over the wire balloon dilatation catheter 10, it is conventional practice to first assemble the guidewire 12 with the balloon catheter 10 and then pass them both in unison through the guide catheter. Alternately, with the present invention, the guidewire 12 may be inserted through the guide catheter by itself. The guidewire is advanced to the coronary ostium and then may be further advanced into the coronary arteries. The guidewire may be of the type described in US-A-4,545,390 to Leary and may be steerable so that it can be manipulated and guided to the desired branch of the coronary arteries to be treated. The progress of the guidewire through the patient's coronary arteries may be monitored fluoroscopically by the physician. The physician also may inject radiopaque contrast liquid through the guide catheter to visualize the coronary anatomy on the fluoroscope. Once the guidewire 12 has been advanced through the stenosis to be treated, the balloon catheter 26 of the present invention is advanced over the guidewire 12 and within the guide catheter 14. The catheter 26 will track smoothly and easily along the guidewire with no significant tendency to buckle. This results from the relatively stiff, pushable nature of the elongate metal tubular proximal segment 28 of the catheter. Additionally, the intermediate and distal segments 30, 32 are supported by the guidewire 12 which provides significant resistance to buckling of the intermediate and distal segments 30, 32. It will be appreciated, therefore, that when the catheter 26 is advanced over the guidewire, the catheter will have significant axial, column support fully along its length. In this regard, it is important to note that the proximal end of the guidewire lumen 44 in the intermediate segment 30 overlaps longitudinally, the distal end of the metal tubular proximal segment 28 that is embedded in the proximal end of the intermediate segment 30. Thus, when the catheter is advanced over the guidewire 12, there is column support fully along the length of the catheter, from its proximal to its distal end. As a result, there is considerably reduced tendency for any portion of the catheter to buckle longitudinally. Consequently, the friction between the balloon dilatation catheter 26 and the guide catheter 14 is substantially reduced thereby enabling the distal end of the catheter to be advanced into distal, remote and tortuous regions of the patient's coro-

nary anatomy.

In order to better grasp the proximal end of the catheter to push it through the guide catheter, a gripping device 56 may be mounted on the proximal segment 28. The gripping device 56 includes a nut 58 which is threaded into a tubular collet 60. The collet 60 and nut 58 are screwed together over the proximal segment 28 to cause the collet 60 to securely grip the proximal segment 28. The position of the gripping device 56 may be adjusted by loosening the nut and repositioning the device.

It should be noted that the length of the intermediate and distal segments 30, 32 are selected so that when the balloon is placed in a very distal region of the coronary anatomy, the juncture of the proximal end of the intermediate segment with the proximal tubular segment 28 is disposed in the descending aorta 18 and does not extend into the aortic arch 20. Thus, the combined length of the intermediate and distal segments 30, 32 should be between 35 to 45 cm long, with a length of 40 cm being preferred for most patients' anatomies. It will be appreciated from the foregoing construction that the flexible intermediate and distal portions 30, 32 will pass easily through the curve of the aortic arch 20 without tendency to buckle because they are fully supported by the guidewire 12. The relatively stiff elongate metal proximal segment 28 does not pass through the aortic arch 20 and maintains its relatively straight configuration so that its pushable characteristics are not compromised. There is minimal tendency of the catheter to dislodge the distal tip of the guide catheter from its position in the coronary ostium.

Should it be desired to exchange the balloon catheter 26 for another catheter, there is no need to use an extended length guidewire. Typically, about 50 cm of the guidewire 12 will protrude exteriorly of the patient. When the catheter 26 is withdrawn, a segment of the guidewire 12 will be exposed at all times, thereby enabling the guidewire 12 to be grasped to maintain its position in the patient. Thus, the catheter 26 may be withdrawn without dragging the guidewire 12 out of position. After the first catheter has been removed, another catheter may be threaded onto the guidewire and advanced through the guide catheter and into the coronary anatomy, guided by the guidewire 12. The catheter constructed in accordance with the invention will be advanced easily, without tendency to buckle or develop high friction within the guide catheter and with no significant tendency to dislodge the guide catheter from its position at the coronary ostium.

From the foregoing, it will be appreciated that the invention provides an improved rapidly exchangeable catheter construction and catheterization method.

It should be understood, however, that the foregoing description of the invention is intended merely to be illustrative thereof.

For example, although the invention has been illustrated in connection with a balloon dilatation catheter, it may also be incorporated in other types of catheters, such as laser catheters, hot tip catheters, infusion catheters, artherectomy catheters and the like.

Having thus described the invention, what I desire to claim and secure by letters patent is:

#### Claims

1. A balloon dilatation catheter for percutaneous transluminal coronary angioplasty, the catheter having proximal, intermediate and distal segments (28,30,32) the intermediate segments (30) being plastic and elongate and attached to the distal end of the proximal segment (28) and having two lumens formed therethrough including an inflation lumen (40) terminating in an outlet port (42) and a guidewire lumen (44) extending parallel to the first lumen and being adapted to receive a guidewire, the guidewire lumen (44) having a proximal opening (46) in the region of the juncture of the intermediate and proximal segments (28,30); the distal segment (32) being attached to the distal end of the intermediate segment (30) and defining an elongate lumen (48) in communication with and a continuation of the distal end of the guidewire lumen (44) of the intermediate segment, and terminating, at its distal tip, in a distal outlet (33); a dilatation balloon (34) having proximal and distal ends, the distal end of the balloon being mounted on the distal segment and the proximal end of the balloon being mounted on the intermediate segment, the interior of the balloon being in communication with the outlet port of the inflation lumen, the proximal segment (28) being elongate and substantially stiffer than the intermediate segment (30);  
characterised in that the proximal segment (28) has a single inflation lumen (36) extending therethrough and is substantially smaller in diameter than the intermediate segment, the proximal segment (28) having sufficient column strength to resist buckling when advanced through a patient's arteries whereby when a guidewire is received in the guidewire lumen (44) the catheter will have continuous column support fully along its length from the proximal end of the tubular shaft to the distal outlet of the distal segment.
2. A balloon dilatation catheter as claimed in claim 1 characterised in that the proximal end (52) of the balloon (34) is mounted to the distal end of the intermediate segment (30) and the distal end (54) of the balloon (34) is mounted to the distal end of the distal segment (32).
3. A balloon dilatation catheter as claimed in claim 2 characterised in that the distal segment (32) is of smaller diameter and is more flexible than the intermediate segment (30).
4. A balloon dilatation catheter as claimed in any of claims 1-3 characterised in that the distal and intermediate segments (32,30) extend over a length of between 35 to 45cm and wherein the overall length of the catheter is between about 145 to 155cm.
5. A balloon dilatation catheter as claimed in claim 4 characterised in that the length of the distal and intermediate segments is about 40cm.
6. A balloon dilatation catheter as claimed in any of claims 1-3 or 5 characterised by a guidewire extending through the guidewire lumen (44).
7. A balloon dilatation catheter as claimed in claim 4 characterised by a guidewire extending through the guidewire lumen (44).
8. A catheter as claimed in claim 4 characterised in that the guidewire is about 175cm long.
9. A catheter as claimed in any of claims 1-3 characterised in that the proximal segment (28) is formed from metal.
10. A catheter as claimed in claim 4 characterised in that the proximal segment is formed from metal.
11. A catheter as claimed in claim 6 characterised in that the proximal segment is formed from metal.

#### Patentansprüche

1. Ballondilatationskatheter für perkutane, durchleuchtende Koronargefäßplastik, wobei der Katheter proximale, mittlere und distale Abschnitte (28,30,32) hat, wobei die mittleren Abschnitte (30) aus Kunststoff und langgestreckt sind, und an dem distalen Ende des proximalen Abschnittes (28) befestigt sind, und zwei Lumen dadurch gebildet haben, die ein Inflationslumen (40) einschliessen, das in einer

Auslassöffnung (42) endet, und ein Führungsdrahtlumen (44), das sich parallel zum ersten Lumen erstreckt, und einen Führungsdraht empfangen kann, wobei das Führungsdrahtlumen (44) eine proximale Öffnung (46) in dem Gebiet der Verbindung der mittleren und proximalen Abschnitte (28,30) hat; wobei der distale Abschnitt (32) an dem distalen Ende des mittleren Abschnittes (30) befestigt ist, und ein langgestrecktes Lumen (48) in Verbindung mit dem distalen Ende des Führungsdrahtlumens (44) des mittleren Abschnittes und eine Fortsetzung davon definiert, und an seiner distalen Spitze in einem distalen Auslass (33) endet; einen Dilatationsballon (34) mit proximalen und distalen Enden, wobei das distale Ende des Ballons auf dem distalen Abschnitt angebracht ist, und das proximale Ende des Ballons auf dem mittleren Abschnitt angebracht ist, wobei das Innere des Ballons in Verbindung mit der Auslassöffnung des Inflationslumens steht, wobei der proximale Abschnitt (28) langgestreckt und wesentlich steifer als der mittlere Abschnitt (30) ist; dadurch gekennzeichnet, dass der proximale Abschnitt (28) ein sich dadurch erstreckendes einzelnes Inflationslumen (36) hat, und einen wesentlich kleineren Durchmesser als der mittlere Abschnitt hat, wobei der proximale Abschnitt (28) ausreichende Säulenstärke hat, um einer Knickung zu widerstehen, wenn er durch die Arterien eines Patienten gebracht wird, wobei, wenn ein Führungsdraht in dem Führungsdrahtlumen (44) empfangen wird, der Katheter kontinuierliche Säulenunterstützung entlang seiner ganzen Länge von dem proximalen Ende der rohrförmigen Welle zum distalen Auslass des distalen Abschnittes haben wird.

2. Ballondilatationskatheter nach Anspruch 1, dadurch gekennzeichnet, dass das proximale Ende (52) des Ballons (34) an dem distalen Ende des mittleren Abschnittes (30) angebracht ist, und das distale Ende (54) des Ballons (34) an dem distalen Ende des distalen Abschnittes (32) angebracht ist.
3. Ballondilatationskatheter nach Anspruch 2, dadurch gekennzeichnet, dass der distale Abschnitt (32) einen kleineren Durchmesser als der mittlere Abschnitt hat und elastischer als der mittlere Abschnitt (30) ist.
4. Ballondilatationskatheter nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die distalen und mittleren Abschnitte (32,30) sich über eine Länge von zwei-

schen 35 bis 45 cm erstrecken, und in dem die Gesamtlänge des Katheters zwischen 145 bis 155 cm ist.

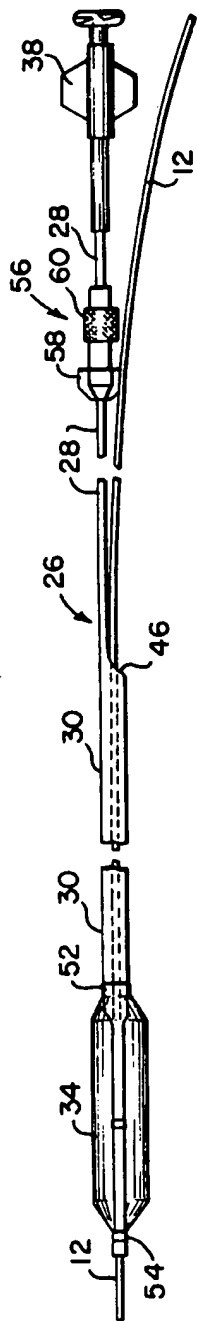
5. 5. Ballondilatationskatheter nach Anspruch 4, dadurch gekennzeichnet, dass die Länge der distalen und mittleren Abschnitte ungefähr 40 cm ist.
10. 6. Ballondilatationskatheter nach einem der Ansprüche 1-3 oder 5, gekennzeichnet durch einen Führungsdraht, der sich durch das Führungsdrahtlumen (44) erstreckt.
15. 7. Ballondilatationskatheter nach Anspruch 4, gekennzeichnet durch einen Führungsdraht, der sich durch das Führungsdrahtlumen (44) erstreckt.
20. 8. Katheter nach Anspruch 4, dadurch gekennzeichnet, dass der Führungsdraht ungefähr 175 cm lang ist.
25. 9. Katheter nach einem der Ansprüche 1-3, dadurch gekennzeichnet, dass der proximale Abschnitt (28) aus Metall gebildet ist.
30. 10. Katheter nach Anspruch 4, dadurch gekennzeichnet, dass der proximale Abschnitt aus Metall gebildet ist.
35. 11. Katheter nach Anspruch 6, dadurch gekennzeichnet, dass der proximale Abschnitt aus Metall gebildet ist.

#### Revendications

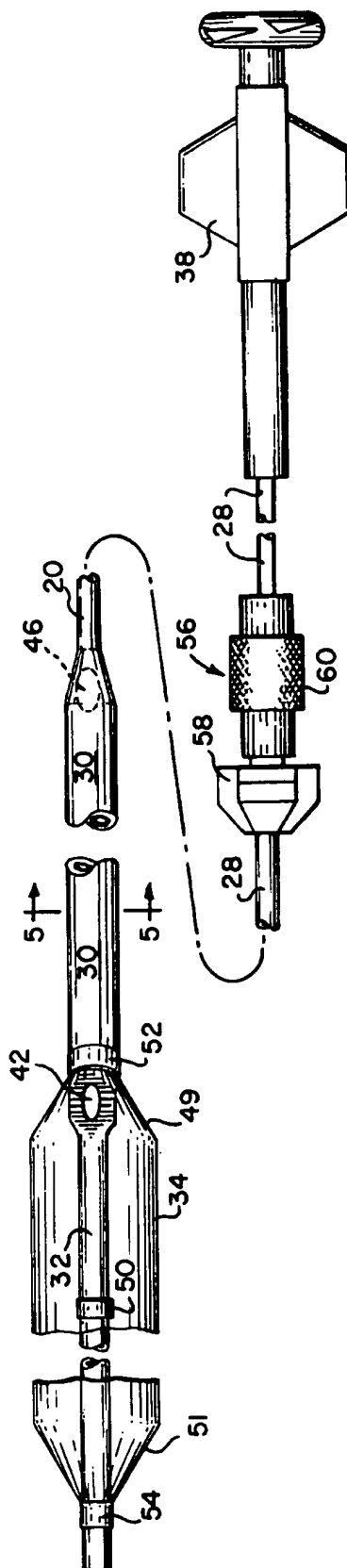
40. 1. Cathéter à ballon de dilatation à l'effet de l'angioplastie coronaire transluminale percutanée, ledit cathéter comportant une série d'éléments à fonction respectivement proximale, intermédiaire et distale (28,30,32), l'élément intermédiaire (30) étant en matière plastique et allongée et attachée à l'extrémité distale de l'élément proximal (28) et formant deux vides y compris un vide de gonflement (40) avec un orifice de sortie (42) et un vide de fil de guidage (44) situé parallèle avec le premier vide et prévu pour recevoir un fil de guidage, le vide de fil de guidage (44) ayant un orifice proximal (46) dans la zone de jonction de l'élément intermédiaire et de l'élément proximal (28,30); l'élément distal (32) étant attaché à l'extrémité distale de l'élément intermédiaire (30) et définissant un vide allongé (48) communiquant avec et en prolongement de l'extrémité distale du vide de fil de guidage (44) d'élément intermédiaire, et se terminant à son extrémité



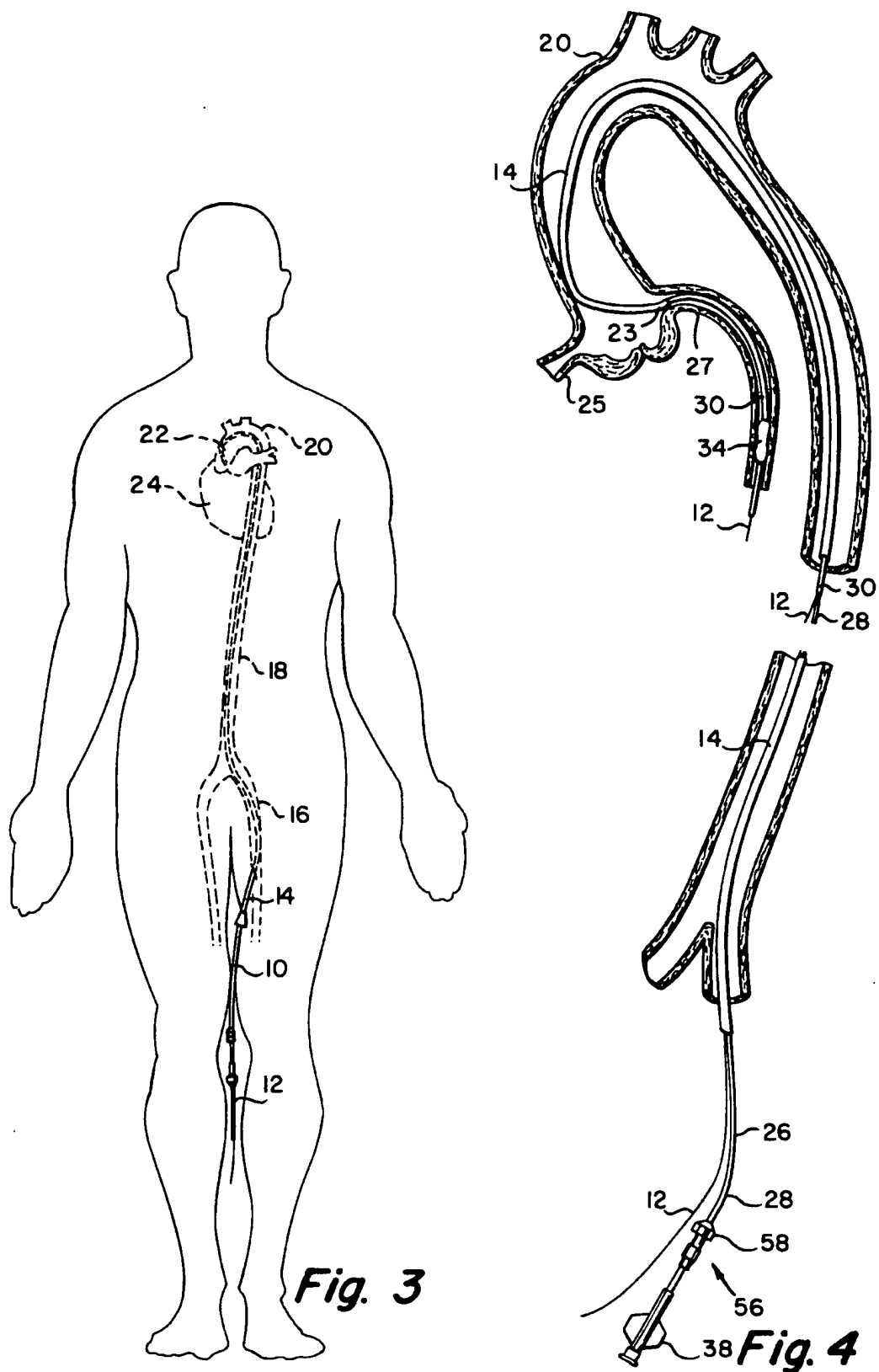
- distale, en orifice distal de sortie (33); un ballon de dilatation (34) ayant des extrémités distale et proximale, l'extrémité distale du ballon étant monté sur l'élément distal et l'extrémité proximale du ballon étant monté sur l'élément intermédiaire, l'intérieur du ballon communiquant avec l'orifice de sortie du vide de dilatation, l'élément proximal (28) étant allongé et essentiellement plus rigide que l'élément intermédiaire (30);
- caractérisé en ce que** l'élément proximal (28) comporte un vide simple de dilatation (36) qui s'étend au travers et prévoit un diamètre essentiellement inférieur au diamètre de l'élément intermédiaire, le segment proximal (28) ayant une résistance de colonne suffisante pour résister au flambage lorsqu'il est avancé dans une artère du patient de façon telle qu'à l'insertion du fil dans le vide de fil de guidage (44), le cathéter est soutenu en colonne continue sur toute sa longueur depuis l'extrémité proximale de tige tubulaire jusqu'à l'extrémité distale de l'élément distal.
2. Cathéter à ballon de dilatation tel que revendiqué à la revendication 1, caractérisé en ce que l'extrémité proximale (52) du ballon (34) est monté sur l'extrémité distale de l'élément intermédiaire (30) et l'extrémité distale (54) du ballon (34) est monté sur l'extrémité distale de l'élément distal (32).
  3. Cathéter à ballon de dilatation tel que revendiqué à la revendication 2, caractérisé en ce que l'élément distal (32) est de diamètre inférieur et plus flexible que l'élément intermédiaire (30).
  4. Cathéter à ballon de dilatation tel que revendiqué aux revendications 1-3, caractérisé en ce que l'élément distal et l'élément intermédiaire (32,30) s'étendent sur une longueur comprise entre 35 à 45 cm, la longueur globale du cathéter étant de l'ordre de 145 à 155 cm.
  5. Cathéter à ballon de dilatation tel que revendiqué à la revendication 4, caractérisé en ce que la longueur de l'élément distal et de l'élément intermédiaire est de l'ordre de 40cm.
  6. Cathéter à ballon de dilatation tel que revendiqué à l'une ou l'autre des revendications 1-3 ou 5, caractérisé par un fil de guidage qui s'étend au travers du vide de guidage (44).
  7. Cathéter à ballon de dilatation tel que revendiqué à la revendication 4, caractérisé par un fil de guidage qui s'étend au travers du vide de
  8. Cathéter à ballon de dilatation tel que revendiqué à la revendication 4, caractérisé en ce que le fil de guidage mesure environ 175 cm de longueur.
  9. Cathéter à ballon de dilatation tel que revendiqué à l'une ou l'autre des revendications 1-3, caractérisé en ce que l'élément proximal (28) est un élément métallique.
  10. Cathéter à ballon de dilatation tel que revendiqué à la revendication 4, caractérisé en ce que l'élément proximal est un élément métallique.
  11. Cathéter à ballon de dilatation tel que revendiqué à la revendication 6, caractérisé en ce que l'élément proximal est un élément métallique.



*Fig. 1*



*Fig. 2*



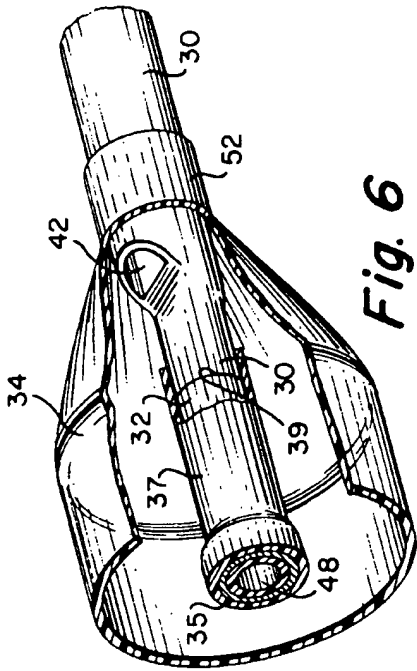


Fig. 6

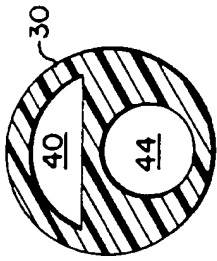


Fig. 5

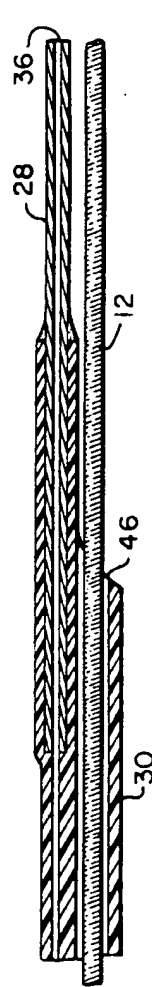


Fig. 7

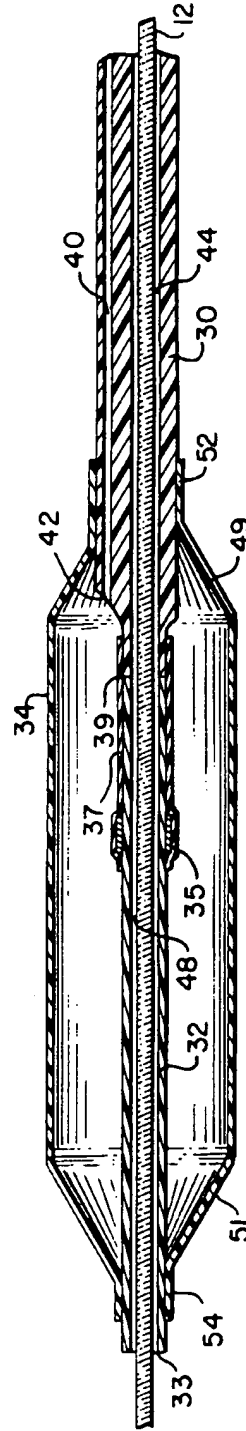


Fig. 8